Exhibit 4

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VIA USPS Certified Mail Return Receipt Requested

U.S. Drug Enforcement Administration
Attn: Anne Milgram, Administrator
8701 Morrissette Drive
Springfield, VA 22152

U.S. Drug Enforcement Administration
Diversion Control Division/DC
Attn: Kristi O'Malley, Senior Advisor to the Administrator
8701 Morrissette Drive
Springfield, VA 22152

Re: Access to Psilocybin for Limited Therapeutic Use Under State and Federal Right to Try Laws

Dear Administrator Milgram:

I write on behalf of Dr. Sunil Aggarwal of the Advanced Integrative Medical Science ("AIMS") Institute who seeks authorization to obtain psilocybin under the Washington and federal Right to Try ("RTT") Acts.[1] He seeks (1) authorization to access psilocybin for therapeutic use under state and federal RTT Acts and (2) immunity from prosecution under the Controlled Substances Act ("CSA"). The federal statute and DEA's regulations permit the agency to grant Dr. Aggarwal's request on various grounds, discussed in detail below.

In recent years, psilocybin has shown enormous promise in early clinical trials in relieving the debilitation anxiety and depression suffered by terminally ill patients. Psilocybin remains a Schedule I controlled substance under the CSA (although Dr. Aggarwal submitted a petition to reschedule dated 2/2/22.)

As a result, no supplier would provide psilocybin to Dr. Aggarwal without DEA's approval. When Dr. Aggarwal sought DEA's guidance regarding how he might obtain such approval, DEA responded that "[a]bsent an explicit statutory exemption to the Controlled Substances Act (CSA)," it lacked "authority to waive any of the CSA's requirements pursuant to the RTT." As detailed below, the agency was mistaken in this assessment of its authority.

Dr. Aggarwal sought judicial review of DEA's determination in the United States Court of Appeals for the Ninth Circuit. *AIMS v. Garland,* 21-70544 (9th Cir. Jan. 31, 2022).[2] The Ninth Circuit recently dismissed the petition, concluding that DEA's decision disclaiming authority to accommodate Dr. Aggarwal's request was not "final" for purposes of judicial review under 21 U.S.C. § 877. Even so, the Court did recognize and describe the interplay between the provisions of the FDCA, which includes the federal RTT , and the CSA. Id. @ 6-10. With

1 See RCW 69.77 et seq. (Washington RTT); Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, Pub. L. No. 115-176, § 1, 132 Stat. 1372, codified at 21 U.S.C. § 360bbb-0a (Federal RTT).

2 Because the Court dismissed the petition for lack of jurisdiction, it did not address the merits of petitioners' claims.

this letter, Dr. Aggarwal formally requests the agency's authorization to obtain psilocybin for therapeutic use for his terminally ill patients as well as immunity from prosecution for this authorized therapeutic use.

Dr. Aggarwal and His Terminally Ill Patients Seek to Exercise Their Rights Under the Federal and State RTT Acts

Dr. Aggarwal is Co-Founder and Co-Director of the AIMS Institute, an integrative oncology clinic based in Seattle, Washington. A well-credentialed palliative care specialist, Dr. Aggarwal is registered with DEA (DEA Registration No. FA4274926) to prescribe schedule II-V drugs. In January 2021, Dr. Aggarwal sought guidance from DEA regarding how he might access the investigational drug psilocybin for therapeutic use with his terminally ill patients, Michal Bloom and Erinn Baldeschwiler, under the federal and state RTT Acts.

In his professional practice, Dr. Aggarwal treats many patients with advanced-stage cancer, including some who suffer from severe anxiety and depression that does not respond to therapy with approved medicines. Michal Bloom and Erinn Baldeschwiler are two such patients. Bloom, a DOJ attorney who retired due to her illness, has been undergoing extensive treatment for advanced ovarian cancer since 2017 with a multitude of burdensome complications. She experiences severe anxiety and depression, which approved FDA therapies have not abated. Baldeschwiler has Stage IV metastatic breast cancer with tumors all over her body. A mother of two, the prospect of an imminent death preventing her from raising her children to adulthood causes her severe mental and emotional pain. She suffers from anxiety and depression that currently approved treatments have failed to address.

Based on his professional experience and assessment of (1) Bloom and Baldeschwiler's condition and symptoms and (2) recent research on psilocybin therapy, including successful clinical trials, Dr. Aggarwal discussed the possibility of psilocybin therapy, including the potential risks and rewards, with Bloom and Baldeschwiler. Both patients indicated a desire to try the treatment and gave informed consent. That is exactly what Dr. Aggarwal seeks to do here: allow terminally ill patients the ability to try an investigational drug therapy, consistent with state and federal RTT Acts and the will of Congress.

Dr. Aggarwal seeks to travel the pathway intended to be created by the state and federal RTT Acts. Washington's RTT law recognized that "the process for approval of investigational drugs … often takes many years" and that patients with terminal illnesses do not have the luxury of waiting until an investigational drug obtains final approval the FDA.[3] Washington legislators voted unanimously to approve access to investigational drugs for "patient[s] with a terminal illness in consultation with the patient's health care provider."[4] At the federal level, Congress embraced the "will of the American people" after a supermajority of states, including Washington, passed RTT legislation.[5] "To open the door to innovative, experimental drugs for terminally ill patients without necessarily compromising the vital work and mission of [FDA]," the federal RTT exempts investigational drugs from the FDA's premarketing approval requirements, permitting state law to govern. Federal RTT thus "empower[s] terminally ill patients and their doctors who, together with the cooperation of the developers of potentially life-saving therapies, should be in charge of making a determination about their own course of treatment."[6]

Dr. Aggarwal's patients qualify for the right to try. Federal RTT allows states to choose whether and to what extent the eligible patient population should have the right to try EIDs, and Washington has made its choice to allow physicians and patients the right to try investigational drugs, weighing the risks and benefits of therapy

[3] RCW 69.77.010.
[4] Id.
[5] 164 Cong. Rec. H4355, H4356 (2018).
[6] Id. At H4360

for the preservation of their quality of life. At the federal level, an "eligible patient" may use an "eligible investigational drug" ("EID") and "no liability in a cause of action shall lie" against a manufacturer, sponsor, prescriber, or dispenser providing EIDs to an eligible patient in compliance with compliance with the federal RTT law. To qualify as an "eligible patient," a person must have (1) been diagnosed with a life-threatening disease or condition, (2) exhausted approved treatment options and is unable to participate in a clinical trial involving the EID and (3) given informed consent regarding the drug. 21 U.S.C. § 360bbb-0a(a)(1). To qualify as an EID, a drug must (1) have completed an FDA-approved Phase 1 clinical trial; (2) not be approved or licensed for any use through the Food, Drug, & Cosmetic Act or the Public Health Service Act. Washington's RTT law operates similarly at the state level.[7]

Applying these RTT Acts to Dr. Aggarwal and his terminally ill patients, psilocybin is an EID. Ms. Bloom and Ms. Baldeschwiler are eligible patients with terminal illnesses who have provided informed consent for the therapy. The federal and state RTT Acts *should* allow them to access psilocybin, but they cannot because of the DEA's failure, as yet, to create a pathway to access.

Dr. Aggarwal's patients are terminally ill, and they are suffering. This suffering could be immediately relieved with access to this investigational drug. He therefore requests a "final decision of the Attorney General" on this urgent matter as soon as possible. *See* 21 U.S.C. § 877.

Dr. Aggarwal and His Patients Have Already Attempted to Exercise Their Rights Under the RTT Acts Via Litigation

In January 2021, Dr. Aggarwal requested DEA provide instructions and guidance on how he could obtain psilocybin for therapeutic use with his suffering terminally ill patients under Washington and federal RTT Acts. He advised that a DEA-registered manufacturer and distributor of psilocybin had agreed to provide the investigational drug on receipt of evidence of DEA's approval.

DEA responded on February 12, 2021, declaring that it could not accommodate Dr. Aggarwal's RTT request. According to DEA, it has "no authority to waive" any of the CSA's requirements to accommodate RTT. DEA provided no avenue to obtain an exception, exemption, or waiver. Instead, it suggested Dr. Aggarwal consider registering as a schedule I researcher under the CSA.

Dr. Aggarwal, AIMS, Michal Bloom, and Erinn Baldeschwiler filed a petition for review of DEA's decision in the United States Court of Appeals for the Ninth Circuit, arguing that DEA was obligated to accommodate petitioners' request for access to psilocybin under RTT. Dr. Aggarwal and his patients' opening brief is attached here as **Exhibit A**, and incorporated herein.[8] The Ninth Circuit dismissed the petition without reaching the merits, concluding that DEA's decision was not a not "a final decision of the Attorney General," under 21 U.S.C. § 877.

DEA Can and Should Grant Dr. Aggarwal's Request Outright and Forthwith

Dr. Aggarwal's request may seem novel or extraordinary. DEA has never yet permitted anyone to obtain access to a schedule I substance under a RTT law. In fact, however, DEA has permitted access to schedule I substances in similar circumstances throughout its history. Recently, for example, it supported physician-initiated therapeutic use of a schedule I cannabis-derived experimental drug by over 300 *children* under FDA's expanded

[7] See RCW 69.77 et seq.
8 Exhibit A outlines the historical and legal background of controlled substance regulation as applied to psilocybin.

access program. In testimony before the Senate Caucus on International Narcotics Control, DEA's then-Deputy Administrator touted the agency's support of access to schedule I controlled substances for therapeutic purposes:

> DEA is committed, consistent with the CSA and the FDCA, to assisting with the healthcare needs of patients. In this regard, the DEA supports research involving CBD and its potential capacity to treat multiple conditions. In June 2014, FDA granted Fast-Track designation to the investigational CBD product, Epidiolex, for study in the treatment of a rare form of childhood epilepsy. FDA has also authorized the use of Epidiolex under Expanded Access, which is designed to facilitate the availability of investigational drug products to patients while those drugs are being studied for approval. DEA supports the use of Expanded Access, which provides access to treatments for patients with serious or immediately life-threatening diseases or conditions, while preserving important protections for those patients. This is a separate process that is available to patients, distinct from the Clinical Trials process. GW Pharmaceuticals, the manufacturer of Epidiolex, has publicly announced that there are over 300 patients being treated through this program, including many pediatric patients with seizure disorders.

Statement of Joseph T. Rannazzissi Dep'y Admin., DEA, Hrg. Before the Sen. Caucus on Int'l Narcotics Control, Cannabidiol: Barriers to Research and Potential Medical Benefits (June 15, 2015).

DEA has every legal and public policy reason to support Dr. Aggarwal's similar request for access to psilocybin for therapeutic use under RTT. After all, expanded access and RTT both involve experimental drugs that have completed Phase I clinical trials. Indeed, Congress described expanded access and RTT as alternative programs that were designed to operate "alongside" each other. 21 U.S.C. § 360bbb-0a(b) note, 132 Stat. 1374-75 (RTT "is consistent with, and will act as an alternative pathway alongside, existing expanded access").

DEA's support of single patient INDs in the context of the Federal Medical Marijuana Program also demonstrates that there is nothing novel or extraordinary about Dr. Aggarwal's request for access to a schedule I substance for therapeutic use. If physicians and pharmacists were permitted to dispense schedule I marijuana to John Randall and the other patients who participated in that program for years, then there is no reason Dr. Aggarwal ought not be permitted to dispense psilocybin to his patients under RTT. It is consistent with prior determinations by DEA, federal and state law, and the underlying public policy rationale that the United States takes care of their own.

Just as the practitioners involved in these programs were permitted to obtain access to schedule I substances without obtaining any additional or special DEA registration, Dr. Aggarwal should be permitted to obtain psilocybin for therapeutic use with his patients without additional registration as well. While Dr. Aggarwal does seek to "dispense" psilocybin, DEA-registered practitioners do not need special registration from DEA to dispense drugs to ultimate users as long as they do so for legitimate medical or scientific purposes. 21 U.S.C. § 829. Given Congress's express endorsement of the dispensing Dr. Aggarwal seeks to undertake—administering an "eligible investigational drug" to an "eligible patient" under RTT—there can be no question that his planned use of psilocybin is legitimate, lawful, and consistent with DEA's mandate and authority. *See also Gonzales v. Oregon*, 546 U.S. 243 (2005) (DEA lacks authority to decide what counts as a legitimate medical purpose under the CSA).

Simply put, the mere fact that the request arose in a novel legal or factual context has never impeded access before, and it should not now.

To the Extent Dr. Aggarwal's Request Requires Additional Registration, DEA Should Waive That Requirement – at Least Temporarily

None of the registration categories available under current DEA regulations applies to Dr. Aggarwal's request. He does not seek to conduct research with psilocybin. Nor does he seek to manufacture it. He does seek to dispense it, but no special registration is generally required when a physician seeks to administer a drug to an ultimate user for legitimate therapeutic purposes.

When confronted with similar circumstances in the past, DEA has either (1) created a new registration classification that does apply to the new activity or (2) concluded no registration was necessary for the activity because it did not constitute an essential link in the closed system of distribution. The development of the reverse distributor industry is instructive on this point.

Reverse distributors collect controlled substances, including schedule I substances, from registrants and either return them to the manufacturer or arrange for their disposal. *See* 68 Fed. Reg. 41222 (July 11, 2003). Because these companies "process" controlled substances, they are in some technical sense "manufacturers" under DEA's definition of that term. *Id.* at 41223 (acknowledging that reverse distributors manufacture controlled substances because they "process them). Nevertheless, DEA permitted them to handle controlled substances for years without registration because "they were not considered an essential link in the closed distribution system that the Controlled Substances Act established …." *Id.* at 223.

As the industry grew, however, reverse distributors came to play a more vital role in the "closed system." In response, DEA sought to require reverse distributors to register as manufacturers. *Id.* But comments from the industry convinced DEA that the regulations applicable to registered manufacturers were not appropriate or necessary in the reverse distribution context. *Id.* Accordingly, DEA created a new registration category especially for reverse distributors. *Id.* In the meantime, it continued to permit the industry to operate without registration. In doing so, DEA did not ignore security and diversion risks. Rather, it imposed those requirements through memoranda of understanding (MOUs) with each company. *Id.*

Just as reverse distributors in the early days did not constitute "an essential link in the closed distribution system that the Controlled Substances Act established," neither do physicians seeking access to controlled substances to treat terminally ill patients under RTT. Indeed, as far as Dr. Aggarwal is aware, he is in a category all his own in this respect. As such, he should not be required to register under the Act at all. *Id.* Instead, DEA should impose whatever diversion controls it deems necessary through an MOU with Dr. Aggarwal. In the event DEA later decides that registration is appropriate and necessary, it could issue establish a special registration category for RTT practitioners at that time, just as it did for reverse distributors.

In its response to Dr. Aggarwal's earlier request for guidance, DEA suggested that Dr. Aggarwal might apply for registration to conduct research with a schedule I substance. But Dr. Aggarwal does not seek to conduct research. Indeed, the point of RTT is to create an avenue for terminally ill patients to access experimental drugs outside of the clinical trial process, for therapeutic use. Common sense dictates that Congress recognized this need in passing the RTT law, given that patients suffering from terminal illness do not have the luxury of time.

Furthermore, requiring Dr. Aggarwal to obtain a schedule I research license would risk violating the CSA itself. Under § 823(f), DEA would need to refer Dr. Aggarwal's "research protocol" to FDA for approval before Dr. Aggarwal could be permitted administer the eligible investigational drug to his eligible patients. Yet the entire purpose of RTT is to permit a patient, doctor, and drug company to proceed to treatment with an eligible investigational drug without having to seek FDA's permission first. *See AIMS*, Op. 8 n.4 (noting that RTT exempts the administration of eligible investigational drugs from the otherwise-applicable FDA-approval

requirements of the FDCA). Requiring registration under § 823(f) in this context re-imposes the FDA-approval requirement that Congress expressly removed from the equation through the enactment of RTT. The CSA prohibits DEA from construing the research-registration requirement of § 823(f) "as in any way affecting, modifying, repealing, or superseding the provisions of the [FDCA]." 21 U.S.C. § 902. Accordingly, DEA may not construe § 823(f) to apply to physicians like Dr. Aggarwal who seek to administer schedule I substances to ultimate users for therapeutic purposes.

To the extent DEA nevertheless believes registration under § 823(f) is required, Dr. Aggarwal asks that DEA waive that requirement at least temporarily because doing so is "consistent with the public health and safety." *Id.* § 822(d). Registration is not necessary for DEA to ensure appropriate security and diversion controls are in place. In these circumstances, DEA can easily impose any diversion controls it deems necessary through an MOU. For the same reasons, to the extent DEA concludes its related regulations apply, *e.g.*, 21 C.F.R. §§ 1301.18, 1301.32, Dr. Aggarwal requests that it make an exception to them to accommodate his request.

Conclusion

For the reasons stated herein, Dr. Aggarwal and AIMS request that DEA authorize him to access psilocybin for therapeutic use with his terminally ill patients under the RTT Acts. Dr. Aggarwal and AIMS further request that DEA grant them immunity from prosecution under the CSA with respect to the therapeutic use of psilocybin described here. To the extent DEA concludes any registration requirement in the CSA or in DEA's implementing regulations applies to this request, Dr. Aggarwal and AIMS request that DEA waive or make an exception as necessary to accommodate this request. Dr. Aggarwal and AIMS are eager to work with DEA to facilitate the granting of this request, including through the execution of an MOU imposing security and diversion controls as necessary.

With this letter, Dr. Aggarwal returns to DEA. He does not seek "guidance" or "advice" but instead the allowance for him to access psilocybin for therapeutic use with his terminally ill patients, consistent with federal and state RTT laws to dramatically improve the quality of life of these patients.

Respectfully submitted,

/s/*Kathryn L. Tucker*

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